K001894
Page 1 of 6

JUL 06 2000

510(k) Summary
E-Scan
Biosound Esaote

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: June 16, 2000

807.92(a)(2)

Trade Name: E-Scan

Common Name: Magnetic resonance diagnostic device

Classification Name(s): System, Nuclear Magnetic Resonance Imaging

Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

Esaote	E-Scan	K990968

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
E-Scan
Biosound Esaote

807.92(a)(5)

Intended Use(s)

The E-scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

K001894
Page 3 of 6

510(k) Summary
E-Scan
Biosound Esaote

Comparison to the cleared device E-scan K990968
Imaging system

Characteristics	E-scan K990968	E-scan modified	Comments
Anatomical regions	Hip, Knee, Foot, Ankle, Leg, Hand, Wrist, Elbow, Forearm, Shoulder, Arm	Hip, Knee, Foot, Ankle, Leg, Hand, Wrist, Elbow, Forearm, Shoulder, Arm	Unchanged
Pulse sequences	Orthogonal Multi-planar Scout Spin Echo T1 (set1) Spin Echo T2 (set2) Multi-Echo (mede) Inversion Recovery (ir) Short TI Inversion Recovery (stir) Spin Echo Half Echo (set1he) Spin Echo Half Scan (set1hf) Turbo SE T2 weighted and Turbo ME (tse, tme) Gradient Echo (ge) Short Time Inversion Recovery Gradient Echo (ge-stir) Gradient Echo 3D (ge3d)	Orthogonal Multi-planar Scout Spin Echo T1 (set1) Spin Echo T2 (set2) Multi-Echo (mede) Inversion Recovery (ir) Short TI Inversion Recovery (stir) Spin Echo Half Echo (set1he) Spin Echo Half Scan (set1hf) Turbo SE T2 weighted and Turbo ME (tse, tme) Gradient Echo (ge) Short Time Inversion Recovery Gradient Echo (ge-stir) Gradient Echo 3D (ge3d) Gradient Echo 3D multi echo (3dde)	The 3dde sequence is described in the section "Device Modification Description"

510(k) Summary
E-Scan
Biosound Esaote

Sequence parameters	set1: TR from 50 ms to 5000 ms step 10 ms TE from 18 ms to 34 ms step 2 ms minimum FOV 100 mm minimum thickness 2 mm tse: TR from 200 ms to 5000 ms step 10 ms TE from 80 ms to 120 ms step 10 ms minimum FOV 140 mm mede: TR from 200 ms to 5000 ms step 10 ms TE first echo 38 ms, second echo 90 minimum FOV 120 mm minimum thickness 3 mm tme: TR from 200 ms to 5000 ms step 10 ms TE first echo 38 ms, second echo 90 ms minimum FOV 140 mm minimum thickness 3 mm	se 18: TR from 50 ms to 5000 ms step 10 ms TE fixed at 18 ms minimum FOV 100 mm minimum thickness 2 mm se 26: TR from 50 ms to 5000 ms step 10 ms TE fixed at 26 ms minimum FOV 100 mm minimum thickness 2 mm se 50: TR from 50 ms to 5000 ms step 10 ms TE fixed at 50 ms minimum FOV 120 mm tse 50: TR from 200 ms to 5000 ms step 10 ms TE fixed at 50 ms minimum FOV 140 mm minimum thickness 3 mm mede: TR from 200 ms to 5000 ms step 10 ms TE first echo 28 ms, second echo 90 minimum FOV 120 mm minimum thickness 3 mm tme: TR from 200 ms to 5000 ms step 10 ms TE first echo 28 ms, second echo 90 ms minimum FOV 140 mm minimum thickness 3 mm 3dde: TR fixed at 34 ms TE fixed at 10 ms FA from 10^{o} to 90^{o} step 5^{o} minimum FOV 140 mm FOV 3D (vol. thickness) from 40 to 200 mm step 10 mm	These are substantially unchanged set1 and tse sequences with a fixed TE value for making the examination procedure easier. The TE fixed at 50 ms makes it possible to obtain a contrast between T1 and T2. These sequences are substantially unchanged. A shorter TE has been used to obtain a more proton density contrast. The 3dde sequence is described in the section "Device Modification Description"

K001514
Page 5 of 6

510(k) Summary
E-Scan
Biosound Esaote

Gradients system

Characteristics	E-scan K990968	E-scan modified	Comments
Control system	digital system based on DSP 3210 16.7 Mips 4 independent channel (X - Y - Z - Bo) DAC 16 bit - updating every 1.8 µs	digital system based on DSP SHARC (66 Mips 0.5 Mbit internal memory) 4 independent channel (X - Y - Z - Bo) DAC 18 bit - updating every 7.2 µs	The new control system is described in the section "Device Modification Description"

Radiofrequency System

Characteristics	E-scan K990968	E-scan modified	Comments
Solenoidal Receiving Coils	Shoulder coil No.1: 17.5 x 12.6 x 14.5 cm (w x d x h)	Shoulder coil No.1: 17.5 x 12.6 x 14.5 cm (w x d x h) Shoulder coil No.5: 16.8 x 7.9 x 15.5 (w x d x h)	The Shoulder coil No.5 is described in the section "Device Modification Description"

Image Processing and Display System

Characteristics	E-scan K990968	E-scan modified	Comments
Image pre-processing Functions		Selectable two levels Hamming filter	The Hamming filter is described in the section "Device Modification Description"
Display monitor	17" Colour 640 x 480 pixel 60 Hz. non-interleaved high contrast power consumption: 130 VA	17" Colour 640 x 480 pixel 60 Hz. non-interleaved high contrast power consumption: 130 VA	Unchanged Accession number: 9831098-13

510(k) Summary
E-Scan
Biosound Esaote

Installation Area Conditions

Characteristics	E-scan K990968	E-scan modified	Comments
RF field intensity	up to 30 dBµV/m with integrated shielding up to 60 dBµV/m with shielding box	up to 30 dBµV/m with integrated shielding up to 40 dBµV/m with shielding box	More precise characterization of the data

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 6 2000

Biosound Esaote, Inc.
c/o Colleen J. Hittle
Official Correspondent
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K001894
E-Scan Magnetic Resonance Diagnostic Device
Dated: June 19, 2000
Received: June 21, 2000
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications For Use

510(k) Number (if known): K001894

Device Name: E-Scan

Indications for Use:

The E-scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001894